

National Organization for Rare Disorders, Inc.®



out of the darkness,
into the light

MEMBER ORGANIZATIONS

Alpha One Antitrypsin Deficiency National Association
Alpha One Foundation
ALS Association
American Brain Tumor Association
American Laryngeal Papilloma Foundation
American Porphyria Foundation
American Syngomyelia Alliance Project
Aplastic Anemia Foundation of America
Association for Glycogen Storage Disease
Association of Gastrointestinal Motility Disorder, Inc.
Batten Disease Support & Research Association
Benign Essential Blepharospasm Research Foundation, Inc.
Charcot-Marie-Tooth Association
Chromosome 18 Registry and Research Society
Cleft Palate Foundation
Cornelia de Lange Syndrome Foundation, Inc.
Cystinosis Foundation, Inc.
Dysautonomia Foundation, Inc.
Dystonia Medical Research Foundation
Dystrophic Epidermolysis Bullosa Research Association (D.E.B.R.A.)
Ehlers-Danlos National Foundation
Epilepsy Foundation of America
Families of Spinal Muscular Atrophy
Foundation Fighting Blindness
Foundation for Ichthyosis & Related Skin Types (F.I.R.S.T.)
Genetic Alliance
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HHT Foundation International, Inc.
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Hereditary Disease Foundation
Histiocytosis Association of America
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International Fibrodysplasia Ossificans Progressiva (FOP) Association, Inc.
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International Rett Syndrome Association
Interstitial Cystitis Association of America, Inc.
Lowe Syndrome Association
Malignant Hyperthermia Association of the United States
Mastocytosis Society
Myasthenia Gravis Foundation
Myeloproliferative Disease Research Center
Myositis Association of America
Mucopolidosis Type IV Foundation (ML4)
Narcolepsy Network, Inc.
National Adrenal Diseases Foundation
National Alopecia Areata Foundation
National Ataxia Foundation
National Foundation for Ectodermal Dysplasias
National Hemophilia Foundation
National Incontinentia Pigmenti Foundation
National Marfan Foundation
National Mucopolysaccharidoses Society, Inc.
National Multiple Sclerosis Society
National Neurofibromatosis Foundation
National PKU News
National Sjogren's Syndrome Association
National Spasmodic Torticollis Association
National Tay-Sachs & Allied Diseases Association, Inc.
National Urea Cycle Disorders Foundation
Neurofibromatosis, Inc.
Osteogenesis Imperfecta Foundation
Parkinson's Disease Foundation, Inc.
Prader-Willi Syndrome Association
Pulmonary Hypertension Association
PXE International, Inc.
Reflex Sympathetic Dystrophy Syndrome Association
Scleroderma Foundation, Inc.
Sickle Cell Disease Association of America, Inc.
The Paget Foundation
Tourette Syndrome Association, Inc.
Trigeminal Neuralgia Association
United Leukodystrophy Foundation, Inc.
United Mitochondrial Disease Foundation
JHL Family Alliance
Wegener's Granulomatosis Support Group, Inc.
Williams Syndrome Association
Wilson's Disease Association

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June 29, 2000

Jane Henney, M.D.
Commissioner
Food and Drug Administration
Parklawn Building, Room 1471 (HF-1)
5600 Fishers Lane
Rockville, MD 20857-1706

RE: Conversion of Prescription
Drugs to O-T-C
FR, 4/27/00

Dear Dr. Henney:

The National Organization for Rare Disorders ("NORD") has learned that the Food and Drug Administration ("FDA") is considering converting a large number of prescription drugs to over-the-counter ("OTC") status. This would include a number of drugs for chronic conditions such as hypertension, hypercholesterol and others.

NORD respectfully requests that the FDA deny OTC status for drugs whose indications are for chronic conditions, especially those that have no obvious symptoms such as high cholesterol or high blood pressure. Physician monitoring is essential for these types of disorders because patients are not in a position to oversee their condition. Patients may be lured into a false sense of security if, as with these conditions, there are no noticeable symptoms. This can lead to patients self-adjusting their dosage, and in some cases ceasing to take the drugs altogether.

Further, converting such vital drugs to OTC status would mean that health insurance plans would no longer reimburse patients for these products. This in turn would increase patients out-of-pocket costs that could lead to many people discontinuing needed medications. For persons with chronic conditions this can be deadly.

There are other categories of pharmaceuticals that the FDA has already switched to OTC status and should continue to be expanded. Allergy medicines, for example, are much more acceptable for OTC classification because patients can clearly see when their symptoms abate and adjust their dosage accordingly. Additionally, nicotine replacements and birth control pills are also acceptable candidates for OTC status because they do not treat a disease, and therefore are taken by choice and not necessity.

ODN-1256

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Associate Members

Acid Maltase Deficiency Association
Acidic Syndrome Newsletter, Inc.
ALS Association/Greater Philadelphia Chapter
American Autoimmune Related Diseases Association
American Behcet's Disease Association, Inc.
American Pseudo-obstruction & Hirschsprung's Disease Society, Inc.
American Self-Help Clearinghouse
Angelview Crippled Children's Foundation
A.T. Project

Ataxia Telangiectasia Children's Project
CDGS Family Network
Canadian Organization for Rare Disorders
Children's Leukemia Foundation/Michigan Children's Living with Inherited Metabolic Diseases
Children's Medical Library
Children's PKU Network
Chromosome Deletion Outreach, Inc.
Chronic Granulomatous Disease Association, Inc.
Consortium of Multiple Sclerosis Centers
Contact A Family
Cooley's Anemia Foundation

Drug Support & Research Foundation
Ehrlich-Goldberg Aplastic Anemia Foundation
Family Caregiver Alliance
Family Support System for North Carolina
Freeman-Sheldon Parent Support Group
Hydrocephalus Association
International Foundation for Alternating Hemiplegia of Childhood
JUMP Foundation
Klippel-Trenaunay Support Group
Late Onset Tay-Sachs Foundation
Les Turner ALS Foundation, Inc.
National Association for Pseudoexanthema Elasticum

National Gaucher Foundation
National Lymphedema Network
National Niemann-Pick Disease Foundation
National Patient Air Transport Helpline
National Spasmodic Dysphonia Association
Organic Acidemia Association
Osteoporosis and Related Bone Diseases National Resource Center
Parents Available to Help (PATH)
Parent to Parent of Georgia, Inc.
Parent to Parent of New Zealand
Rare and Expensive Disease Management Program

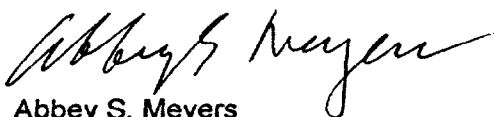
Recurrent Respiratory Papillomatosis Foundation
Restless Legs Syndrome Foundation
Sarcoid Networking Association
Shwachman Syndrome Support Group
Sickle Cell Disease Association of Texas Gulf Coast
Society for Progressive Supranuclear Palsy, Inc.
Sotos Syndrome Support Association
Sturge-Weber Foundation
Takayasu's Arteritis Association
Treacher Collins Foundation
Vanore les Maladies Lysosomes/France

* Associations are joining continuously
For newest listing, please contact the
NORD office.

Jane Henney, M.D.
June 29, 2000
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NORD believes that the FDA must fully consider all the repercussions of moving drugs for serious and chronic diseases to OTC status, including first and foremost the American consumer's welfare. Therefore, we request that you maintain the current status of those medications that are necessary for chronic medical conditions.

Very truly yours,

A handwritten signature in cursive script, appearing to read "Abbey S. Meyers".

Abbey S. Meyers
President

ASM:aa